

**REMARKS**

The present invention relates to drug release systems comprising a shape memory material (SMP-material) and at least one drug.

In the Office Action dated June 24, 2010, claims 20 - 22 were withdrawn from consideration, claims 1 - 16, 18, and 19 were rejected, and claims 2, 6, 13, and 16 were objected to.

The Examiner's acknowledgment and consideration of the Information Disclosure Statement filed April 15, 2005 is appreciated, as is the Examiner's withdrawal of the alleged "non-responsive" response earlier with respect to the election of species issue.

The Office Action objected to claims 2, 6, 13, and 16 as failing to further limit the subject matter of a previous claim are set forth at page 3 of the Office Action. Lastly, claims 1 - 16, 18 and 19 were rejected under 35 U.S.C. § 102(b) based on Langer et al (US Patent 6,388,043), based on Langer et al's general teachings with respect with shape memory polymer (SMP) and the Examiner noting that bioactive materials may be included therewith.

In the present Amendment, Applicant has incorporated claim 4 into claim 1, and claims 7, 12, and 14 have been amended to independent form. Claims 2, 4, and non-elected claims 20 - 22 have been canceled, thus obviating any issues relating to those claims. Also, minor amendments have been made to other claims to improve the grammatical form thereof.

With respect to the objection to claim 6, Applicant respectfully traverses, and submits that claim 6 does further limit claim 1, in that claim 1 does not limit the stimuli that may be used, whereas claim 6 limits the stimuli to temperature, light, or a combination thereof. Thus, claim 6 differs in scope from claim 1, and the objection thereto under 37 C.F.R. §1.75(c) should be withdrawn. Similarly, claim 13 differs in scope from claim 12 on which it depends, because

claim 12 does not recite that the SMP-material controls the rate of release of the drug. Lastly, Applicant also respectfully traverses the objection to claim 16, and Applicant notes that claim 16 differs in scope from claim 1 and that claim 16 is specifically limited to controlling the drug release based on hydrolytic degradation of the shape memory material. As noted above, claim 2 has been canceled, thus obviating the objections thereto.

Applicant respectfully traverses the rejections of the claims under 35 U.S.C. § 102(b) for the reasons explained below.

The drug release system according to independent claims 1, 7, 12, and 14 involves the shape memory effect used to vary or to initiate the drug release rate.

Langer et al. (US 6,388,043 B1) disclose shape memory polymers (SMP materials) and their use for biomedical applications, such as drug delivery systems among many others (col. 16, lines 22-29). Langer et al further disclose to incorporate drugs within polymer compositions, which can locally or systemically deliver the incorporated agents following administration to a patient (col. 15, lines 52-59).

However, Langer et al is silent as to how these agents are released from the polymer. Usually drug release has been accomplished by degradation of the polymer. Thus, Langer et al fail to teach or suggest that shape memory effect can be used to vary the rate of drug release.

Accordingly, Applicant respectfully submits that Langer does not anticipate the present claims, and specifically fails to disclose a drug release system comprising a shape memory material and at least one drug, as well as the specific further features recited in the independent and dependent claims.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby earnestly solicited. If any points remain in issue

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby earnestly solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned attorney at the local Washington, D.C., telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

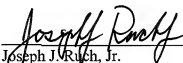
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